SCOTUS Overturn of the ACA May Invalidate Biosimilar Pathway

Summary

The 351(k) biosimilars pathway was legally established under the Biologics Price Competition and Innovation Act (BPCIA) provision of the Patient Protection and Affordable Care Act (ACA) of 2010. Since the passage of the ACA, 28 biosimilars have been approved by the Food & Drug Administration (FDA) along with the promulgation of policy that also applies to all biologics, including the creation of a suffix within the nonproprietary name of these products. Additionally, substantial case law has been made with respect to intellectual property pertaining to biologics. With the legality of the ACA currently under scrutiny, the future of BPCIA and biosimilars is uncertain.

Background

Shortly after its passage, several efforts to repeal or overturn the ACA were attempted.
latest court case, Texas challenged the validity of the ACA—asserting that with the individual mandate penalty set to $0, the mandate was no longer enforceable as a tax and therefore unconstitutional. The US District Court for the Northern District of Texas agreed, holding the ACA unconstitutional and holding that the individual mandate was inseverable from the remainder of the ACA, meaning that striking the individual mandate causes the entire law to fail. The US Court of Appeals for the Fifth Circuit concurred with the district court on the individual mandate issue but disagreed with severability. Ultimately, the case has been appealed and accepted by SCOTUS, with oral arguments set for November 10, 2020.

Next Steps

The Supreme Court of the United States (SCOTUS) will not hear the case until after the 2020 election, and a decision would likely be expected by mid-2021. The newly confirmed Justice Amy Coney Barrett is widely speculated to cement a conservative majority on the Court and is expected to hear California v. Texas. It is possible that the Court may uphold the ACA writ large, likely by affirming the unconstitutionality of the individual mandate but severing it from the remaining law. This outcome is the most likely outcome considering the Roberts Court’s perspective on the 2012 NFIB v. Sebelius ruling. Additionally, since BPCIA is contained within a separate title from the individual mandate and has little to do with health insurance coverage, the 351(k) biosimilars pathway may remain in place.

It is possible, though very unlikely, that the Court will overturn the entire ACA. This casts a shadow of doubt on the biosimilars pathway, and it is unclear what the FDA would do in the fallout. The FDA may convert biosimilars (approved under the 351(k) pathway that was added by BPCIA) to 351(a) biologics (currently originator biologics), similar to the agency’s treatment of the “rollover” of the ~100 biologics previously regulated as drugs on March 23, 2020. These rollover products themselves were transferred under the ACA and have the potential to be reverted to being regulated as drugs (505(b)(1) and 505(b)(2)).

In the unlikely event the ACA were overturned in its entirety, Congress could decide to reauthorize BPCIA as standalone legislation (which is how it was originally introduced and added to ACA as a “pay for”), regardless of the party in control. But that may come with changes, such as proposals to reduce originator biologic exclusivity, change the current use of suffixes, alter the FDA review timelines, and others.

While all eyes are on the SCOTUS’s decision for the ACA, originator and biosimilar biologics sponsors should pay particular attention to what happens to the BPCIA.
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